UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP.,

Plaintiff,

v.

Case No. 2:21-cv-10312

Hon. F. Kay Behm

BLUEWILLOW BIOLOGICS, INC.; ROBIN ROE 1 through 10, gender neutral fictitious names; and ABC CORPORATION 1 through 10 (fictitious names).

Defendants.

DEFENDANT/COUNTER-PLAINTIFF BLUEWILLOW BIOLOGICS, INC.'S MOTION FOR SUMMARY JUDGMENT

Pursuant to Federal Rule of Civil Procedure 56, Defendant/Counter-Plaintiff BlueWillow Biologics, Inc. ("BlueWillow"), by and through its undersigned counsel, Foley & Lardner LLP, respectfully moves for summary judgment of non-infringement, no remedy, and invalidity. The stipulated order entered January 23, 2023 extended the page limits for briefs in support of summary judgment motions to 40 pages. Dkt. 55; *see also* Text-Only Order dated February 7, 2023.

On January 17, 2023, BlueWillow's counsel met and conferred with counsel for Plaintiff/Counter Defendant Trutek Corp. ("Trutek"), explained the nature and bases of this Motion, and requested concurrence in the relief sought. Trutek did not concur.

First, Trutek cannot meet its burden to establish that BlueWillow has infringed the asserted claims of U.S. Patent No. 8,163,802 ("the '802 Patent"). Second, Trutek should not be awarded any relief for its claims of infringement – injunctive relief or damages – because BlueWillow is no longer selling the accused product and because Trutek has failed to meet its burden of demonstrating any pre-suit or post-suit damages, including for the reasons provided in BlueWillow's Motion to Exclude Damages. Dkt. 39. Third, each of the asserted claims of the '802 Patent are anticipated by prior art U.S. Application No. 2009/0143476 ("Baker") when applying Trutek's own infringement theories.

For the reasons stated in the accompanying Brief in Support, the Court should grant BlueWillow's Motion for Summary Judgment.

Dated: March 28, 2023

Respectfully submitted,

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BLUE WILLOW'S BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

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STATEMENT OF ISSUE PRESENTED

1. Whether the Court should grant summary judgment of non-infringement of the '802 patent.

2. Whether the Court should grant summary judgment that Trutek is entitled to zero damages and no injunctive relief with respect to its claims of infringement of the '802 patent, and if so, whether Trutek is no longer entitled to a jury trial.

3. Whether the Court should grant summary judgment finding the asserted claims of the '802 patent invalid.

BlueWillow's answers: **Yes**.

Trutek's answers: **No**.

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I. INTRODUCTION

Defendant BlueWillow Biologics, Inc. ("BlueWillow") respectfully submits that summary judgment should be granted in its favor on (1) non-infringement, (2) remedy and (3) invalidity, for the reasons stated herein.

First, Trutek cannot satisfy its burden of proving that BlueWillow has infringed any of the asserted claims of U.S. 8,163,802 ("the '802 patent"). Admissions by Trutek and its experts demonstrate that there is no legitimate factual dispute that BlueWillow's NanoBio® Protect product does not (1) form a thin film upon application to the nasal passages having "adequate impermeability" or (2) contain Benzalkonium Chloride (BZK) in an amount sufficient to allow NanoBio® Protect to perform the functions recited in and required by the asserted claims. Summary judgment of non-infringement is also appropriate because Trutek has failed to proffer admissible evidence and expert testimony demonstrating that NanoBio® Protect meets each element of the asserted claims.

Second, Trutek cannot satisfy its burden of proving that it is entitled to any remedy should BlueWillow be found to infringe at least one valid claim of the '802 patent. For the reasons detailed in BlueWillow's Motion to Exclude Damages (Dkt. 39), Trutek should be precluded from offering any damages related evidence or theories at trial. In the absence of admissible evidence or expert testimony on any damages theory, it is appropriate for the Court to award Trutek zero damages.

Likewise, there can be no factual dispute that Trutek has failed to plead or demonstrate that the patented products were marked in accordance with 35 U.S.C. § 287(a), and thus, no pre-suit damages should be awarded. Finally, as Trutek has repeated conceded, BlueWillow is no longer selling the only accused product, NanoBio® Protect. As such, Trutek's request for injunctive relief is moot.

Third, and alternatively, if Trutek's infringement theories are credited, the asserted claims are necessarily and inherently anticipated under 35 U.S.C. § 102 by U.S. Application No. 2009/0143476 ("Baker"), a prior art patent application that discloses the same composition as the accused product.

II. FACTUAL BACKGROUND

BlueWillow is a clinical-stage biopharmaceutical company focused on developing intranasal vaccines for various medical conditions. (Dkt. 9, Counterclaim, ¶ 6.) BlueWillow also developed and sold NanoBio® Protect, an over-the-counter nasal antiseptic that uses BlueWillow's proprietary technology to deliver benzalkonium chloride (BZK), a common skin antiseptic that has been used in over-the-counter products for more than 75 years. (*Id*. ¶ 7.) NanoBio® Protect is now discontinued and is no longer sold in the U.S. (Dkt. 28 at 2; Dkt. 28-1 at ¶ 7.)

A. Procedural Background

On February 10, 2021, Trutek filed suit alleging infringement of the '802 patent against BlueWillow and a single accused product, NanoBio® Protect. (Dkt.

9, Counterclaim ¶ 6; Dkt. 1, Complaint). Trutek has asserted infringement of claims 1, 2, 6 and 7 of the '802 patent. BlueWillow responded to the complaint by asserting defenses of non-infringement and invalidity of the '802 patent. (Dkt. 9.)

On June 2, 2022, the Court denied Trutek's motion to amend the complaint to add allegations of infringement against additional products. (Dkt. 32.)

On June 27, 2022, the Parties exchanged opening expert reports. Trutek submitted two reports from Dr. Ermakov and Mr. Burns describing testing of the BlueWillow and Trutek products, in addition to a report from Dr. Lemmo on infringement that relies on the Ermakov and Burns testing. (Declaration of Liane M. Peterson ("Peterson Decl."), Ex. 3.) Trutek did not serve an expert report on damages. BlueWillow submitted one report from Dr. Amiji directed to invalidity of the '802 patent asserted claims. (Declaration of Mansoor M. Amiji ("Amiji Decl.), Ex. 1.) On August 15, 2022, the Parties exchanged responsive expert reports. (*Id*., Ex. 2; Peterson Decl., Exs. 4, 6.) Trutek's responsive report from Dr. Lemmo is limited in scope, responding only to a narrow subset of BlueWillow's invalidity defenses, and does not address BlueWillow's invalidity defenses based on US 2009/0143476 (Baker). Trutek's responsive report from Mr. Haidri provides legal opinions from a patent lawyer who is not qualified to testify about issues of patent validity under controlling case law. On September 29, 2022, the Parties exchanged

reply expert reports on issues of invalidity (Amiji) and infringement (Lemmo). (Amiji Decl., Ex. 3; Peterson Decl., Ex. 5.)

On September 26, 2022, BlueWillow filed a motion *in limine* to exclude Trutek's damages-related theories and evidence (Dkt. 39), which remains pending.

On November 17, 2022, the Court denied Trutek's second motion to amend the complaint to add allegations of willful infringement. The motion was denied on grounds of undue delay, prejudice and futility because Trutek's claims "would not survive a motion to dismiss." (Dkt. 50, at 3-8.) On January 10, 2023, the Court issued its claim construction opinion and order. (Dkt. 53).

On March 15, 2023, BlueWillow filed two *Daubert* motions to exclude (1) the expert report and testimony of Trutek's expert Amirali Haidri on issues related to invalidity (Dkt. 56) and (2) the expert reports and testimony of Trutek's experts Alexei Ermakov and Shane Burns on issues related to infringement (Dkt. 57).

B. Overview of the '802 Patent and Asserted Claims

The '802 patent was granted on April 24, 2012 from Application No. 12/467,271, filed on May 16, 2009. (Peterson Decl., Ex. 1.) The '802 patent claims priority to two U.S. provisional applications, filed on July 7, 2008 and August 3, 2008. (*Id*.) Based on the effective filing date of the '802 patent, it is governed by the "pre-AIA" version of the patent statute.

Trutek has asserted claims 1, 2, 6 and 7 of the '802 patent ("the Asserted Claims") in this litigation against BlueWillow. Claims 1 and 2 are independent claims, with claim 1 directed to a method of using a formulation and claim 2 directed to a formulation, each of which require the formulation to function in a particular manner. As described by Trutek and its experts, elements (a), (b) and (c) of the independent claims relate to the "catch," "hold" and "kill" functions that the claimed formulation must perform. (Dkt. 37; Dkt. 51-1, PageID 1054.) Claims 6 and 7 depend from independent claim 2, and thus, necessarily include all of the elements of claim 2. The Asserted Claims are reproduced below:

> 1. A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation where a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:
> a) electrostatically attracting the particulate matter to the thin film;
> b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
> c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.
>
> 2. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:
> a) electrostatically attracts the particulate matter to the thin film;
> b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,

c) inactivates the particulate matter and renders said particulate matter harmless.

6. The formulation of claim 2 wherein the at least one cationic agent is Benzalkonium Chloride.

7. The formulation of claim 2 wherein the at least one cationic agent is Benzalkonium Chloride or Lysine HCL.

The '802 patent specification describes the invention as "products and methods that involve the use of products heretofore developed for restricting the flow of airborne contaminants into the nasal passages by creating an electrostatic field in an area near about the nasal passages." (Peterson Decl., Ex. 1 at 1:63-67.) The claimed formulation "capture[s] and hold[s] the contaminants including viruses, bacteria, and other harmful microorganisms or toxic particulates, inactivate[s] them dermally outside the body and render[s] them harmless." (*Id*. at 2:3-7.) The '802 patent also describes the various functions (or "Objects of the Invention") to be performed by the claimed compositions and methods:

- "capable of capturing particulates and microorganisms" (*Id*. at 2:66-67)
- "capability to hold it for a duration from being dislodged in to the air stream again" (*Id*. at 3:1-3)
- "will inactivate, kill, or render harmless a microorganism, which has been captured and held by the composition" (*Id*. at 3:7-9)

The '802 patent specification includes Tables 1-10, each of which purport to describe "[e]xamples of typical formulations" and "various embodiments of the Present Invention." (*Id*. at 5:52 – 10:8.) The formulations listed in Tables 1-10 are

described in terms of their ingredients with a range provided for each ingredient. (*Id*.) Each of the tables that list Benzalkonium Chloride (BZK) as an ingredient specify a range of 0.25% to 1%. (*Id*.)

C. BlueWillow's NanoBio® Protect

NanoBio® Protect is a "liquid nanoemulsion consisting of nano-droplets that range between 300-600 nanometers in size." (Peterson Decl., Ex. 3 (Lemmo Report) at 11 and Ex. D.) NanoBio® Protect contains Benzalkonium Chloride (BZK) in a concentration of 0.13% by weight. (*Id*., Ex. 3 at 9 ("the product contains 'benzalkonium chloride (0.13%) antiseptic.'").)

NanoBio® Protect is discontinued and BlueWillow no longer sells the product in the U.S. (Dkt. 28 at 2; Dkt. 28-1 at ¶ 7.) The U.S. Food and Drug Administration ("FDA") issued a warning letter to BlueWillow dated August 3, 2021, directed to NanoBio® Protect and related statements on BlueWillow's website. (Peterson Decl., Ex. 5 (Lemmo Reply Report) at Ex. 4.)

III. LEGAL STANDARD

A court should grant summary judgment "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). No genuine issue of material fact exists if, by viewing the evidence in a light most favorable to

the nonmoving party, a reasonable jury could not return a verdict for that party. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

"Summary judgment is appropriate if a party, after adequate opportunity for discovery, 'fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial.'" *Tolton v. American Biodyne, Inc.*, 48 F.3d 937, 941 (6th Cir. 1995) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)). "The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff." *Anderson*, 477 U.S. at 252. "If the evidence presented is merely colorable, or is not significantly probative, summary judgment may be granted." *Anderson*, 477 U.S. at 249-50 (citations omitted).

When deciding summary judgment, only admissible evidence should be considered. *See Wiley v. United States*, 20 F.3d 222, 225-26 (6th Cir. 1994) (quoting *Beyene v. Coleman Sec. Servs., Inc.*, 854 F.2d 1179, 1181 (9th Cir. 1988)). "Summary judgment is as appropriate in a patent case as it is in any other type of case." *Desper Prods., Inc. v. QSound Labs, Inc.*, 157 F.3d 1325, 1332 (Fed. Cir. 1998) (internal citation omitted).

IV. ARGUMENT

As a matter of law, Trutek cannot meet its burden to prove infringement, recoverable damages, or injunctive relief. Further, if Trutek's infringement theories are credited, then summary judgment of invalidity is warranted because the prior art discloses the same composition as the accused product and thus, anticipates the asserted claims under Trutek's own infringement theories.

A. Summary Judgment of Non-Infringement Should Be Granted[1]

"To establish literal infringement, all of the elements of the claim, as correctly construed, must be present in the accused system." *TechSearch, LLC v. Intel Corp*., 286 F.3d 1360, 1371 (Fed. Cir. 2002). Moreover, "it is error for a court to compare in its infringement analysis the accused product or process with the

[1] Although Trutek sought leave to amend to assert a claim of willful infringement, Trutek's request was denied on grounds of undue delay, prejudice and futility. Dkt. 50. Thus, the operative pleading governing Trutek's claims in this litigation does not contain a claim for willful infringement. Despite the Court's clear ruling, Trutek maintains it is permitted to present claims of willful infringement to the jury. To the extent the Court deems that permissible, summary judgment of no willful infringement is nevertheless warranted. The Court has already held that Trutek's "speculative and conclusory" assertion of willful infringement "would not survive a motion to dismiss." *Id*. at 8. Specifically, Trutek's claims are premised entirely on post-suit knowledge of the '802 patent. However, "merely pleading awareness of the patent 'is not enough to sustain a willful infringement claim.'" *Id*. at 7-8 (citing *Mich. Motor Techs. LLC v. Volkswagen Aktiengesellschaft*, 472 F. Supp. 3d 377, 384–85 (E.D. Mich. 2020)). Nor has Trutek proffered any evidence of pre-suit knowledge, a requirement that many courts have required for a finding of willful infringement. *See, e.g*., *ZapFraud, Inc. v. Barracuda Networks, Inc.*, 528 F. Supp. 3d 247, 252 (D. Del. 2021) (explaining that "the purpose of filing a lawsuit is to seek relief for existing claims, not to form the basis for new claims").

patentee's commercial embodiment or other version of the product or process; the only proper comparison is with the claims of the patent." *Zenith Lab'ys, Inc. v. Bristol-Myers Squibb Co*., 19 F.3d 1418, 1423 (Fed. Cir. 1994). "[B]ecause a dependent claim narrows the claim from which it depends, it must 'incorporate . . . all the limitations of the claim to which it refers.'" *Alcon Research, Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1367 (Fed. Cir. 2012) (citing 35 U.S.C. § 112, ¶ 4).

Summary judgment is "appropriate where the patent owner's proof is deficient in meeting an essential part of the legal standard for infringement, because such failure will render all other facts immaterial." *TechSearch*, 286 F.3d at 1369 ("general assertions of facts, general denials, and conclusory statements are insufficient to shoulder the non-movant's burden," *id*. at 1372). "A party may not overcome a grant of summary judgment by merely offering conclusory statements." *Moore U.S.A., Inc. v. Standard Register Co*., 229 F.3d 1091, 1112 (Fed. Cir. 2000).

1. NanoBio® Protect Does Not Form a "Thin Film" having "Adequate Impermeability"

'802 Patent claim 1, element (b) requires "holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film." Claim 2, element (b) contains similar

requirements. Trutek has failed to meet its burden to demonstrate that this claim element, as properly construed, is present in NanoBio® Protect.

Rather than addressing "adequate impermeability" or the requisite "adhesion" and "cohesion," Dr. Lemmo's analysis of element (b) addresses only whether "the product exhibits impermeability." The entirety of Dr. Lemmo's analysis in his opening report directed to claim element (b) reads as follows:

> When administered to a user's nostrils, the product forms a thin film that adheres to the skin or tissue of his nasal passages. If that were not the case, the liquid would instantly drip out of the user's nose. Instead, "the droplets persist on the skin for four or more hours." Further, the "droplets significantly hydrate skin to avoid dryness and cracking that can allow germs in." Thus, the product exhibits impermeability.

(Peterson Decl., Ex. 3 at 11.) These general and conclusory assertions do not demonstrate that NanoBio® Protect forms a "thin film" upon application having "adequate impermeability," as required by all of the asserted claims.

As explained by BlueWillow's expert, Dr. Amiji, the material cited by Dr. Lemmo in his report (attached to Lemmo's report as Exhibit D) does not indicate that NanoBio® Protect "forms a thin film on the nasal passages, let alone a thin film that persists for [f]our hours or operates to electrostatically attract and inhibit particulate matter from infecting an individual by creating a permeability barrier." (Amiji Decl., Ex. 2 at ¶ 54.) With respect to claim element (b) and Dr. Lemmo's assertion that NanoBio® Protect "exhibits impermeability" because the droplets "significantly hydrate skin to avoid dryness or cracking that can allow the germs

in," Dr. Amiji explains that a "person of ordinary skill in the art would understand that a formulation such as NanoBio Protect, which purports to alleviate dryness in the nasal passage, does not necessarily do so as a result of any 'adjustment' in the 'cohesion of the formulation' or by existing as an impermeable thin film on the nasal passages." (*Id*. at ¶¶ 56-58.)

Further, Trutek and Dr. Lemmo both made repeated assertions during claim construction demonstrating why there is no material dispute that NanoBio® Protect does not form a "thin film" having "adequate impermeability", as required by the properly construed claims. In his declaration submitted in support of Trutek's claim construction positions, Dr. Lemmo described element (b) as a "hold" function, *i.e*., a "protective concept based on adhesive and cohesive properties." (Dkt. 40, PageID 731-753 (Declaration of Edward A. Lemmo Ph.D. in Support of Trutek Corp.'s Claim Construction Brief) at ¶ 32.)

When addressing the meaning of element (b) and the "hold" function, Dr. Lemmo explained that the adhesive and cohesive properties of the formulation create a "**barrier of impermeability** trapping a significant number of these particles outside the nasal passageway." (*Id*. at ¶¶ 32-33 (emphasis added).) He further explained that the formulation would be "incomplete if the formulation did not have the adhesive and cohesive properties required to hold the particles in place" and that "[a]ttraction by electrostatic forces is enhanced by the holding

properties of adhesion and cohesion, and the holding properties set up the formulation's biocidic ingredients to inactivate and kill bioactive particles that are held in place by the formulation." (*Id*. at ¶ 35.)

At his deposition, Dr. Lemmo confirmed the same meaning of "adequate impermeability," explaining that the "hold" function of claim element (b) operates through the adhesive and cohesive properties of the thin film, which sets up a "barrier of impermeability" that exists as a **physical barrier**:

Q: . . . the entire sentence reads that, "This sets up a barrier of impermeability trapping a significant number of these particles outside the nasal passageway"; right?

A: Correct.

Q: Okay. So the claimed formulation, once applied, it creates a thin film on the surface of the skin; right?

A: That's correct.

Q: And that thin film, as recited in the claims, is impermeable, meaning that it creates a physical barrier?

A: It – yes, it creates a physical barrier outside of the body.

Q: Okay. And then that physical barrier traps those harmful particles from being inhaled into the respiratory system, right?

A: That's correct.

Q: . . . In paragraph 37, you conclude that the claim term "adequate impermeability is a property of the applied formulation that allows the harmful particles to be held in place for a sufficient time to be inactivated"; right?

A: That's correct.

Q: Okay. And so like we just talked about, that's a physical barrier that allows the harmful particles to be held in place –

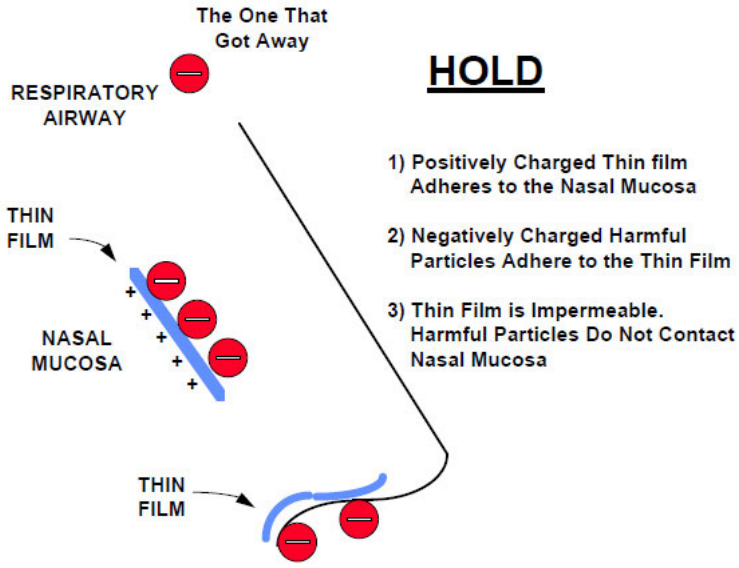
A. That's correct.

Q. – for a sufficient time? Okay.

A. That's right.

(Peterson Decl., Ex. 7 (Lemmo Tr.) at 141:2 – 142:8.)

Trutek's arguments during claim construction are also consistent with Dr. Lemmo's testimony that "adequate impermeability" of the thin film, as required by element (b) of the asserted claims, refers to a **physical barrier**. More specifically, Trutek's slides contain the following picture, depicting the "thin film" (in blue) as a **solid, continuous, physical barrier** on the nasal mucosa:



(Dkt. 51-1, PageID 1056 (Trutek's Markman Presentation Slides).)

Turning to the accused product, NanoBio® Protect is a nanoemulsion that does not form a "thin film" upon application having "adequate impermeability" because it does not form a physical or continuous barrier. It is undisputed that NanoBio® Protect is a nanoemulsion. (Peterson Decl., Ex. 3 at 11 (citing Exhibit D) ("Nanobio Protect product is a liquid nanoemulsion consisting of nano-droplets

that range between 300-600 nanometers in size.").) As explained by Dr. Lemmo, "[b]y their very nature, nanoemulsion droplets exhibit an electrostatic charge which causes them to repel one-another." (*Id*. at 8.) Dr. Lemmo confirmed during his deposition that the nanoemulsion droplets of NanoBio® Protect **do not form a continuous, physical barrier** on the skin **because they continue to exist as separate droplets**:

Q. . . . And you understand that NanoBio Protect is a nanoemulsion product?

A. Yes.

Q. Okay. So at the bottom of this paragraph, you have a sentence that's underlined where you state that, "By their very nature, nanoemulsion droplets exhibit an electrostatic charge which causes them to repel on-another" –

A. Yes.

Q. Okay. So when a nanoemulsion is applied to the skin, it exists as individual droplets?

A. Yes.

Q. And then after application to the skin, they remain as separate droplets on the skin –

A. Right.

Q. – as a result of that electrostatic charge; right?

A. Right. I believe that's the way it is. And they would coalesce[] to a single liquid mass if they were not electrostatically charged.

Q. So, in other words, when applied to the skin, they don't form a continuous layer on the skin. They still exist as droplets.

A. That is my understanding of how the technology works. Because you have positive and negative charge built into the structure of the nanoemulsion.

(Peterson Decl., Ex. 7 (Lemmo Tr.) at 222:24 – 224:1.)

Stated another way, if the individual droplets of NanoBio® Protect do not

form a continuous layer on the skin, then there must necessarily be holes or gaps in that layer. Without this continuous layer, NanoBio® Protect does not form a physical "barrier of impermeability trapping a significant number of these particles outside the nasal passageway," an element that both Trutek and Dr. Lemmo have conceded is required by element (b) of the asserted claims, *i.e.*, the "hold" function provided by the term "adequate impermeability." (Dkt. No. 40 (Lemmo Decl.) at ¶¶ 32-33, 35, 52; Peterson Decl., Ex. 7 (Lemmo Tr.) at 141:2 – 142:8, 222:24 – 224:1.) In addition, Dr. Lemmo conceded that the BlueWillow marketing materials he relied on do not describe NanoBio® Protect as forming a thin film to trap or hold particles. (Peterson Decl., Ex. 7 (Lemmo Tr.) at 271:8-11.)

For the foregoing reasons, summary judgment of non-infringement of asserted claims 1, 2, 6 and 7 is appropriate because NanoBio® Protect does not form a "thin film" having "adequate impermeability," as properly construed and conceded by Trutek and its expert.

2. NanoBio® Protect Does Not Contain a Sufficient Amount of BZK to Satisfy the Claimed Functions

The asserted claims of the '802 patent contain a number of specific functional claim elements, *i.e.*, the "catch," "hold" and "kill" functions described by Trutek and its experts. (Dkt. No. 40 (Lemmo Decl.) at ¶¶ 31; Dkt. 51-1, PageID 1054.) At other times, Trutek refers to these same functions as "attract," "hold" and "inactivate." (Dkt. 37 at 24.) More specifically, independent claims 1 and 2

(and dependent claims 6 and 7, each of which incorporate the elements of claim 2), require the claimed formulation to:

- "electrostatically inhibit[] harmful particulate matter from infecting an individual" (claim preamble);
- "electrostatically attract[] the particulate matter to the thin film" (claim element (a) ("attract" or "catch"));
- "hold[] the particulate matter in place . . ." (claim element (b) ("hold")); and
- "inactivat[] the particulate matter" and "render[] said particulate matter harmless" (claim element (c) ("kill" or "inactivate")).

To prove infringement, Trutek must demonstrate that NanoBio® Protect performs each of these functional claim requirements. *TechSearch, LLC*, 286 F.3d at 1371; *see also INVT SPE LLC v. Int'l Trade Comm'n*, 46 F.4th 1361, 1375 (Fed. Cir. 2022) ("To determine whether an accused device is a device with the 'capability' of performing the recited functions, it must be able to perform those functions when it is activated and put into operation."). Based on the admission of Trutek's experts during deposition and related positions taken during claim construction, there is no legitimate factual dispute that NanoBio® Protect does not perform each of the functions required by the asserted claims.

The '802 patent specification includes Tables 1-10, each of which purport to describe "[e]xamples of typical formulations" and "various embodiments of the Present Invention." (Peterson Decl., Ex. 1 at 5:52 – 10:8.) The formulations listed in Tables 1-10 are described in terms of their ingredients with a range provided for

each ingredient. (*Id*.) Each of the tables that list Benzalkonium Chloride (BZK) as an ingredient specify a range of 0.25% to 1%. (*Id*.)

As explained by Trutek during claim construction, the "specification provides ten example formulations. According to the specification, all of these example formulations function as recited in claims 1, 2, 6 and 7." (Lemmo Decl., Dkt. 40 at ¶ 41.) Dr. Lemmo further explained that "[a]s long as the composition of ingredients remains within the specified ranges, the example formulations should function as disclosed." (*Id*.) In rendering its opinion and order on claim construction, the Court relied on Trutek's expert testimony, finding that "the technology will function properly **so long as the concentrations are within the assigned ranges**." (Dkt. 53 at 19 (citing ECF 40, PgID 713, 746 (Trutek Responsive Markman Brief and Lemmo Decl.) (emphasis added).)

It is undisputed that NanoBio® Protect contains 0.13% by weight of Benzalkonium Chloride (BZK) – less than half the amount required by the '802 patent as disclosed in the ten tables (0.25% to 1%). (Peterson Decl., Ex. 3 (Lemmo Opening Report) at Ex. D, page 4 ("NanoBio Protect's active ingredient is 0.13% benzalkonium chloride, which is regulated by the FDA as a skin antiseptic and has been used in humans for over 75 years.").) Dr. Lemmo also confirmed during his deposition that 0.25% to 1% is the effective amount of BZK required to function in the claimed invention:

Q: . . . And then I saw that a few of the tables also list benzalkonium chloride?

A. Yes.

Q. And benzalkonium chloride is always identified in the range of .25 to 1 percent?

A. Yes, I think that's related to the standard that's allowable.

Q. Okay. So is that the effective concentration of benzalkonium chloride that's needed to function in the claimed invention?

A. I believe so.

Q. Okay

A. Yes.

(Peterson Decl., Ex. 7 at 133:10-22.) Trutek's other expert (Haidri) also agrees, stating that benzalkonium chloride is a "known biocidic agent" that is "used as an ingredient in the '802 Patent formulations, and functions effectively in a concentration of 0.25% to 1% by weight." (Peterson Decl., Ex. 6 at 38.)

Trutek cannot credibly argue now, that a product containing only 0.13% BZK will function as required by the '802 patent asserted claims, given that the amount of BZK is less than half of what is required. *See* Dkt. 53 at 19 (Court's claim construction order finding that "the technology will function properly so long as the concentrations are within the assigned ranges"). Trutek and its experts took this position when defending against claims of indefiniteness, and the court relied on Trutek's positions in rendering its claim construction opinion decision. Trutek should not be permitted to distance itself from these admissions and summary judgment is warranted on this ground as well.

3. Trutek Has Otherwise Failed to Satisfy its Burden of Proving Infringement

In addition to the two claim elements addressed above that are not present in NanoBio® Protect, Trutek has failed to satisfy its burden of proving infringement for several other reasons.

For example, any argument that the 0.13% of BZK present in NanoBio® Protect is enough for the accused product to satisfy each of the functional claim elements of the asserted claims should be disregarded as wholly unsupported and conclusory. *TechSearch*, 286 F.3d at 1372 ("general assertions of facts, general denials, and conclusory statements are insufficient to shoulder the non-movant's burden"); *Moore*, 229 F.3d at 1112 ("A party may not overcome a grant of summary judgment by merely offering conclusory statements."). In his deposition, Dr. Lemmo conceded that varying the percentage of any ingredient from what is disclosed in Tables 1-10 of the '802 patent can impact the potency, efficacy and consistency of the formulation, as well as its adhesive and cohesive properties. (Peterson Decl., Ex. 7 at 135:12 – 136:11.) Despite this acknowledgement, and knowing that NanoBio® Protect only contains 0.13% BZK, Dr. Lemmo did not undertake any analysis or investigation to determine whether a formulation containing only 0.13% BZK would function as required by the '802 patent claims.

Further, Trutek and its experts have not conducted any relevant or admissible testing, or identified any other admissible evidence, demonstrating that

NanoBio® Protect will (1) "electrostatically inhibit[] harmful particulate matter from infecting an individual"; (2) "electrostatically attract[] the particulate matter to the thin film"; (3) "hold[] the particulate matter in place . . ." ; or (4) "inactivat[] the particulate matter" and "render[] said particulate matter harmless." While Trutek engaged two individuals to test NanoBio® Protect, their testing does not demonstrate infringement for two key reasons.

First, all of the testing should be excluded under Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) for the reasons stated in BlueWillow's Motion to Exclude the Expert Reports and Testimony of Alexei Ermakov and Shane Burns. (Dkt. 57.) In turn, Trutek's infringement expert, Dr. Lemmo, relied on the results of Burns and Ermakov testing in reaching his opinions on infringement. (Peterson Decl., Ex. 3 at 9-10 (stating he relied on Dr. Ermakov's and Mr. Burns' work in forming his opinions).) Dr. Lemmo did so without confirming their qualifications, without having any role in designing the test conditions, without confirming the soundness of their testing methodology, and without confirming the identity, manufacturing or expiration date of any of the samples. (*Id*., Ex. 7 at 227:3 – 228:13, 229:17 – 230:3, 231:19 – 232:15.) Nor could Dr. Lemmo even address whether pigskin is a suitable substrate for assessing how the accused product would function when applied to human nasal passages, an element that is also required by the asserted claims. (*Id*. at 247:12-18.)

Second, even if the Burns and Ermakov testing is found to be admissible, it is irrelevant to the question of whether NanoBio® Protect practices the asserted claims. At most, the Burns and Ermakov testing merely asserts that NanoBio® Protect exhibits an electrostatic charge within "the same order of magnitude" as Trutek's product. However, comparisons between the accused product and a purported commercial embodiment of the claimed invention are not evidence of infringement. *Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1481-82 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 924 (1984) ("Infringement is not determined by … comparison between commercial products sold by the parties."). Indeed, Dr. Lemmo repeatedly bases his infringement opinions on this improper comparison. (Peterson Decl., Ex. 3 at 9-10; Ex. 7 at 255:13-20 (asserting that the products are "similar").) Moreover, as explained by Dr. Amiji, merely establishing that NanoBio® Protect exhibits an electrostatic charge does not prove that the electrostatic charge is sufficient to actually perform the functions required by the asserted claims, *i.e.*, electrostatically inhibit infection and/or electrostatically attract particulate matter. (Amiji Decl., Ex. 2 at ¶ 52.)

Taking away the flawed Burns and Ermakov testing, all that remains of Trutek's infringement case are Dr. Lemmo's wholly unsupported and conclusory opinions. For example, Dr. Lemmo admitted that at the time he prepared his infringement opinions, he did not even know the full list of ingredients contained

in NanoBio® Protect, relying only on the known presence of BZK in the formulation (at a concentration lower than what is required by the '802 patent). (Peterson Decl., Ex. 7 at 45:3-20.) This is consistent with Dr. Lemmo's opinions provided in his opening report, where he identifies the BZK component of NanoBio® Protect as both the cationic agent and biocidic agent required by the '802 patent claims. (Peterson Decl., Ex. 3 at 1-2 (stating that "the formulation contains benzalkonium chloride" which is a "known cationic agent" and a "known biocidic agent".) When discussing the requirements of the asserted claims, Dr. Lemmo further explains that the "cationic agent in the thin film produces a positively charged electrostatic field in the vicinity of the nasal passages" and that the "biocidic agent in the formulation functions to inactivate or inhibit the capture harmful particles so as to render them harmless." (*Id*. at 7.) In other words, Dr. Lemmo has clearly pointed to the BZK component of NanoBio® Protect as the ingredient responsible for at least the following claim limitations: "electrostatically inhibiting," "electrostatically attracting," "inactivating the particulate matter" and "rendering said particulate matter harmless."

However, Dr. Lemmo has acknowledged that other ingredients in the formulation can impact the overall positive charge, possibly going so far as to neutralize the charge altogether. (Peterson Decl., Ex. 7 at 124:19 – 125:24.) Likewise, Dr. Lemmo also conceded that the amount of any neutralizing ingredient

and the pH of the environment where the formulation is used can also impact the overall charge of the formulation. (*Id*. at 125:25 – 126:7.) Given that Dr. Lemmo did not even know what other ingredients are contained in NanoBio® Protect, there is no way that he could have assessed whether those ingredients could impact the overall charge of NanoBio® Protect provided by the only cationic agent he identified (BZK), and what impact, if any, it would have on the ability to electrostatically attract and inhibit harmful particulate matter as required by the asserted claims.

Similarly, Dr. Lemmo assumed that NanoBio® Protect would "form[] a thin film that adheres to the skin or tissue" of the nasal passages because "[i]f that were not the case, the liquid would instantly drip out of the user's nose." (Peterson Decl., Ex. 3 at 11.) Dr. Lemmo, however, confirmed that he did not do any testing to confirm whether NanoBio® Protect actually operates in this manner. (*Id*., Ex. 7 at 269:10-23.) Moreover, the BlueWillow marketing materials that Dr. Lemmo relied on indicate that NanoBio® Protect prevents germs by hydrating the skin, not by creating an impermeable thin film that acts as a physical barrier. (*Id*., Ex. 3 at Ex. E page 1.) Dr. Lemmo conceded that these are different mechanisms of action. (*Id*., Ex. 7 at 273:13-17.) Each of these conclusory and unsupported opinions offered by Trutek's expert are insufficient to overcome summary judgment of non-infringement. *TechSearch*, 286 F.3d at 1371; *Moore*, 229 F.3d at 1112.

B. Summary Judgment of No Remedy Should be Granted

1. Trutek Has Not Met Its Burden to Prove Damages

As detailed in BlueWillow's motion *in limine* (Dkt. 39), Trutek has wholly failed to disclose a damages calculation, identify any evidence supporting a damages theory, or disclose any expert witness that will testify as to damages. Accordingly, exclusion of all damages evidence and theories is required (including those based on a reasonable royalty and/or lost profits). *See MicroStrategy Inc. v. Business Objects, S.A.*, 429 F.3d 1344, 1356-57 (Fed. Cir. 2005). Courts will not permit introduction of a damages calculation or theory to be submitted to a jury when disclosed for the first time in response to a motion *in limine* or summary judgment. *See id.*; *Voice Int'l Inc. v. Oppenheimer Cine Rentals LLC*, No. LA CV15-08830-JAK (KSx), 2020 WL 1229735, at *3-8 (C.D. Cal. Feb. 4, 2020).

Trutek's failure to timely conduct damages-related discovery precludes recovery of any damages. *See Santana v. U.S. Tsubaki, Inc.*, 87 F.3d 1315, 1315 (6th Cir. 1996) (affirming zero damages based on lack of evidence where plaintiff failed to demonstrate why he was unable to conduct discovery within the allotted timeframe). In addition, courts will not award patent damages without supporting evidence or based on mere speculation and conjecture. *See Whitserve LLC v. Computer Packages, Inc.*, 694 F.3d 10, 29-33 (Fed. Cir. 2012); *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 868-73 (Fed. Cir. 2010).

"While the patent damages statute provides that a patentee is 'in no event' to be awarded 'less than a reasonable royalty for the use made of the invention by the infringer,' 35 U.S.C. § 284, this does not absolve a patentee of its obligation in litigation to meet its burden of proof . . . ." *AOS Holding Co. v. Bradford White Corp.*, No. CV 18-412-LPS, 2021 WL 5411103, at *38 (D. Del. Mar. 31, 2021). Rather, Plaintiff is required to provide competent evidence of damages:

> [T]he failure to present competent evidence regarding how the factfinder should perform the reasonable royalty calculation is fatal to [a] claim for reasonable royalty damages. A factfinder cannot be asked to speculate from numbers unsupported by law and divorced from expert guidance, but rather the factfinder needs either clear guidance from an expert about how to apply complex calculations or simple factual proofs about what this patentee has previously accepted in factually analogous licensing situations.

Unicom Monitoring, LLC v. Cencom, Inc., No. CIV.A 06–1166 (MLC), 2013 WL 1704300, at *8 (D.N.J. Apr. 19, 2013) (granting summary judgment with respect to monetary damages absent expert); *see also Veritas Operating Corp. v. Microsoft Corp.*, No. 2:06-cv-00703-JCC, 2008 WL 657936, at *34 (W.D. Wash. Jan. 17, 2008) (granting summary judgment on patent damages absent expert).

A damages theory absent evidence, which is necessary "[t]o prevent the hypothetical from lapsing into pure speculation," should not be entertained. *Riles v. Shell Exploration & Prod. Co.*, 298 F.3d 1302, 1311 (Fed. Cir. 2002). Trutek has no expert and has not disclosed any evidence that could be used to reliably

reconstruct the market or assist a jury in determining the outcome of a hypothetical negotiation. This requires damages to be limited to zero (or alternatively, nominal):

> Although we have not upheld a zero royalty rate in a case with an affirmative infringement finding – and have stated that it is 'unlikely' that a hypothetical negotiation would result in a zero royalty rate – we have previously stated that "in a case completely lacking any evidence on which to base a damages award, the record may well support a zero royalty award."

TecSec, Inc. v. Adobe Inc., 978 F.3d 1278, 1291 (Fed. Cir. 2020); *see also AOS*, 2021 WL 5411103, at *38 (awarding nominal damages of $1 where there was no evidence of the number of infringing sales); *Devex Corp. v. General Motors Corp.*, 667 F.2d 347, 363 (3rd Cir. 1981) (affirming award of zero damages for lack of evidence and saying: "The statute requires the award of a reasonable royalty, but to argue that this requirement exists even in the absence of any evidence from which a court may derive a reasonable royalty goes beyond the possible meaning of the statute.").

Nor has Trutek disclosed any of the evidence required to satisfy its burden of proof as to lost profits. *See, e.g.*, *Grain Processing Corp. v. Am. Maize-Prod. Co.*, 185 F.3d 1341, 1350 (Fed. Cir. 1999 ("To prevent the hypothetical from lapsing into pure speculation, this court requires sound economic proof of the nature of the market and likely outcomes with infringement factored out of the economic picture."); *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 875 F.3d 1369,

1380-82 (Fed. Cir. 2017) (explaining lost profits factors and overturning jury verdict where insufficient evidence was provided to establish lost profits).

In short, Trutek was required to, but did not provide evidence sufficient to establish a legally permissible damages award at any time in this litigation, and has no damages expert to even belatedly offer such theories. As such, summary judgment of no damages is appropriate as a matter of law.

2. Trutek Has Not Met Its Burden to Prove Pre-Suit Damages

"The patentee bears the burden of pleading and proving he complied with § 287(a)'s marking requirement." *Arctic Cat Inc. v. Bombardier Recreational Prod. Inc.*, 876 F.3d 1350, 1366 (Fed. Cir. 2017); *see also Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1111 (Fed. Cir. 1996). "Whether [a patentee's] articles have been duly marked or not is a matter peculiarly within his own knowledge; and, if they are not duly marked, the statute expressly puts upon him the burden of proving the notice to the infringers before he can charge them in damages." *Dunlap v. Schofield*, 152 U.S. 244, 248 (1894). "A patentee's licensees must also comply with § 287, because the statute extends to 'persons making or selling any patented article for or under [the patentee].'" *Arctic Cat*, 876 F.3d at 1366 (quoting 35 U.S.C. § 287(a)); *see also Maxwell*, 86 F.3d at 1111. The marking must be "substantially consistent and continuous in order for the party to avail itself of the constructive notice provisions of the statute." *Maxwell*, 86 F.3d at 1111.

The notice requirements of Section 287(a) are backed by strong policy considerations as "a patentee who sells or permits the sale of unmarked, patented articles misleads others into believing they are free to make and sell an article actually covered by patent." *Arctic Cat*, 876 F.3d at 1366. The Federal Circuit has further explained that "the marking statute serves three related purposes: (1) helping to avoid innocent infringement; (2) encouraging patentees to give public notice that the article is patented; and (3) aiding the public to identify whether an article is patented." *Id.*

Notably, Trutek did not plead compliance with § 287(a), either by itself or by any of its licensees, in its Complaint. Dkt. 1. Nor has Trutek alleged that it provided actual notice to BlueWillow of its alleged infringement prior to the filing of the Complaint. *Id*. For this reason alone, it is appropriate for the Court to grant summary judgment that Trutek is not entitled to recover any damages for pre-suit infringement. *Arctic Cat*, 876 F.3d at 1366 ("The patentee bears the burden of pleading and proving he complied with § 287(a)'s marking requirement.").

Moreover, Trutek has not offered any admissible or probative evidence that it has complied with the notice provisions of § 287(a).[2] For example, Dr. Lemmo

[2] Likewise, Trutek has not disclosed any evidence that its licensee(s) of the '802 Patent have complied with the marking requirements of § 287(a). [redacted] Peterson Decl. at ¶ 11.

provided a single, unsupported sentence in his responsive report stating the "patent number of the '802 Patent is clearly marked for every unit sold in the United States." (Peterson Decl., Ex. 4 (Lemmo Responsive Report) at 12-13; *see also* Ex. 6 (Haidri Responsive Report) at 77 (asserting all products were marked without identifying any evidence).) When asked the basis for this assertion, Dr. Lemmo stated that it was based solely on his own purchase of Trutek's NasalGuard product, which occurred sometime in 2020, and that he had no knowledge of whether the '802 patent number was marked on any of Trutek's NasalGuard products at any other point in time. (*Id*., Ex. 7 at 213:16 – 215:13). Thus, Trutek has not proven that the required patent marking pursuant to § 287(a) was "substantially consistent and continuous." *Maxwell*, 86 F.3d at 1111.

Additionally, to the extent Trutek argues that the marking requirement does not apply to the asserted method claims, this argument is inapposite. While "the notice provisions of section 287 do not apply where the patent is directed to a process or method," the Federal Circuit has "held that if a single patent contains both apparatus claims and method claims, the marking requirement applies to all the claims." *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1334 (Fed. Cir. 2012) (citing *Am. Med. Sys., Inc. v. Med. Eng'g Corp.*, 6 F.3d 1523, 1538-39 (Fed. Cir. 1993)). Thus, because Trutek is asserting both apparatus

claims (claims 2, 6 and 7) and method claims (claim 1), Trutek must prove compliance with § 287(a) to be entitled to pre-suit damages.

3. A Permanent Injunction Should Not Issue

A permanent injunction is not awarded automatically upon a finding of infringement of a valid patent claim. The Supreme Court has made clear that the traditional four-factor test for injunctive relief applies in patent cases. *eBay Inc. v. MercExchange*, L.L.C., 547 U.S. 388, 391 (2006). Accordingly, to be awarded an injunction, Trutek must demonstrate: (1) it has "suffered an irreparable injury"; (2) remedies at law are "inadequate to compensate for that injury"; (3) equitable relief is warranted when balancing the hardships of the parties; and (4) the "public interest would not be disserved." *Id*.

Here, it is undisputed that the only accused product, NanoBio® Protect, is no longer being sold. (Dkt. 28 at 2; Dkt. 28-1 at ¶ 7.) In addition, the warning letter issued by the FDA to BlueWillow concerning the prior sale of NanoBio® Protect renders it unlikely that the product will ever be re-introduced into the U.S. market. (Peterson Decl., Ex. 4 (Lemmo Reply Report) at Ex. 4.) Moreover, BlueWillow's products in development are all intranasal vaccine products, a business that Trutek is not engaged in. As such, there is no material dispute that Trutek and BlueWillow are not competitors, and there is no ongoing irreparable injury to Trutek. [redacted]

[redacted]

[redacted] (Peterson Decl., Ex. 9 (TT 000112).)

Courts have declined to issue injunctions on similar facts. *E.g.*, *Paice LLC v. Toyota Motor Corp.*, 504 F.3d 1293, 1303 (Fed. Cir. 2007) (affirming denial of injunction where parties were not competitors and where patentee had previously offered licenses). As such, judgment should be entered in BlueWillow's favor that no injunctive relief should be awarded to Trutek.

4. Trutek Is Not Entitled to a Jury Trial

The Federal Circuit consistently holds that when a patentee cannot obtain damages, and can only obtain equitable relief (such as an injunction), whether through its own actions or the actions of the court, they are not entitled to a jury trial on infringement issues. In both *Tegal Corp. v. Tokyo Electron America, Inc.*, 257 F.3d 1331 (Fed. Cir. 2001) and *In re Technology Licensing Corp.*, 423 F.3d 1286 (Fed. Cir. 2005), the Federal Circuit held that a patentee who was entitled to only equitable relief at trial was not entitled to a jury trial. As discussed above, summary judgment of no damages is appropriate. To the extent Trutek is permitted to seek equitable or injunctive relief, just as in *Tegal* and *Technology Licensing*, its jury demand should be struck. In both cases the patentees pursued damages, but proceeded at trial solely on equitable issues.

The Federal Circuit's decision in *Tegal* is particularly instructive. In that case, the patentee "initially requested a jury trial for its patent infringement suit" that "sought both injunctive relief and damages." *Id.* at 1338. However, shortly before trial, the patentee "informed the district court judge that it was dropping its claim for damages." *Id.* In response, the court issued an order that the trial would proceed without a jury, both as to patentee's allegations of infringement and the defendant's affirmative defenses. *Id.* After the court found that the patents were valid and willfully infringed, the defendant appealed, contending that it had a right to a trial by jury even though the only remedy sought by the patentee was an injunction. *Id.* at 1338-1339.

In finding that no right to a jury existed, the court explained that in 18th century England, allegations of patent infringement could be raised in both actions at law and suits in equity, and that the choice depended upon the relief sought. *Id.* at 1340. "If the patentee sought an injunction and an accounting, the patentee went to a court of equity," but if "the patentee sought only damages, a court of law was used." *Id.* Applying this framework, the Federal Circuit held that where the patentee's only interest was in an injunction, the nature of the action was equitable and no right to a jury existed.

In other words, the Federal Circuit's analysis makes clear that a patentee, such as Trutek, who does not have a claim for damages, is treated under the

Seventh Amendment historical test in exactly the same way as a patentee who never brought a damages claim at all. *See* 257 F.3d at 1340 ("given Tegal's interest only in an injunction, it is clear that Tegal would have needed, in eighteenth century England, to bring its case in a court of equity"); *see also Midland Ross Corp. v. Sunbeam Equip. Corp.*, 52 F.R.D. 573, 575-76 (W.D. Pa. 1971) ("Under the provisions of 35 U.S.C. § 287, it would therefore appear that plaintiff has no claim for damages resulting from the infringement and therefore could not have initially demanded a jury trial"). Accordingly, because Trutek is unable to put forward a triable issue on damages, its request for a jury trial should be struck and this case should proceed as a bench trial, if at all.[3]

C. Summary Judgment of Invalidity Should Be Granted

Applying Trutek's own infringement theories, there is no material disputed issue of fact that the prior art published patent application US 2009/0143476 ("Baker application") anticipates each of the asserted claims of the '802 patent. A "prior art reference which expressly or inherently contains each and every

[3] If the Court determines that Trutek is not entitled to damages or an injunction, there is no further relief the Court can award to Trutek even upon a favorable decision on Trutek's infringement claim (assuming any triable issues of fact remain). BlueWillow respectfully submits that such a decision would be in the form of declaratory relief only, a claim that Trutek has not pled in the operative Complaint, and that it would be proper to dismiss the case in its entirety. Dkt. 1 (Trutek's Complaint does not plead any claims for declaratory relief).

limitation of the claimed subject matter anticipates and invalidates." *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1379 (2003).

35 U.S.C. § 102(e) provides that "a person shall be entitled to a patent unless (e) the invention was described in – (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent."

US 2009/0143476 was filed on October 30, 2007 as Appl. No. 11/928,427, which in turn, is a continuation of Appl. No. 10/179,547 filed on June 25, 2002. The application was published on June 4, 2009. (Peterson Decl. at ¶ 3 and Ex. 2.) As such, the earliest effective date of US 2009/0143476 is at least as early as June 25, 2002, *i.e.*, before the earliest priority date of the '802 patent (July 7, 2008). Thus, US 2009/0143476 is prior art to the '802 Patent under 35 U.S.C. § 102(e).[4]

The Baker application is assigned to the Regents of the University of Michigan. (Peterson Decl., Ex. 2.) The technology disclosed therein is licensed to BlueWillow and forms the basis for the nanoemulsion technology used in NanoBio® Protect. (Amiji Decl., Ex. 3 at ¶ 50.) As explained by Dr. Amiji, Baker discloses "antimicrobial nanoemulsion compositions comprising cationic containing compounds" in addition to the "use of quaternary ammonium

[4] Trutek has not contested the prior art status of US 2009/0143476 (Baker).

compounds for broad-spectrum antimicrobial agents (e.g., benzalkonium chloride)" for use in "nasal and topical forms, including application to the skin or nasal mucosa." (*Id*., Ex. 1 at ¶¶ 98, 101.)

Trutek's expert on invalidity issues (Amirali Haidri) largely agrees with Dr. Amiji's explanation of Baker, stating in his expert report that:

> Like its parent application, Baker '476 also teaches an antimicrobial composition contained within an oil-in-water nanoemulsion adjuvant. Among the disclosed embodiments are those where the composition is administered nasally. The nanoemulsion adjuvant is able to form a thin film. The function of the composition is to prevent or treat infection or disease resulting from various microbes. Among the disclosed ingredients are at least one cationic agent and at least one biocide. In at least one embodiment, the composition contains benzalkonium chloride as an ingredient.

(Peterson Decl., Ex. 6 at 67.) Mr. Haidri goes on to concede that "Baker '476 teaches the CATCH and KILL elements" of the asserted claims, but is "silent regarding the HOLD element" because there is no express reference to "adjusting the adhesion and cohesion of the nanoemulsion to achieve adequate impermeability." (*Id*. at 68.) In other words, Haidri concedes that Baker expressly discloses elements (a) and (c) of claims 1 and 2 as well as the additional limitations of claims 6 and 7. With respect to element (b) however, Haidri incorrectly states the applicable legal framework, stating that "[i]f the reference is silent regarding a single element in the claim, then anticipation is not achieved." *Id*.

However, the Federal Circuit has made clear that even if a prior art reference is "silent" as to a particular claim element, the missing claim element may be inherent and will anticipate if that inherent limitation "is the 'natural result flowing from' the explicit disclosure of the prior art." *Schering*, 339 F.3d at 1379 (citing *Eli Lilly & Co. v. Barr Lab'ys., Inc*., 251 F.3d 955, 970 (Fed. Cir. 2001)).

Dr. Amiji has provided unrebutted testimony that the "HOLD" element of the asserted claims is inherently disclosed by Baker, *i.e*., it is the "natural result" flowing from use of the compositions disclosed by Baker. First, he explains that the three functions of "catch, hold and kill" are "not performed by three separate ingredients. Benzalkonium chloride as disclosed in Baker '476 imparts positive charge that can "CATCH," "HOLD," and "KILL." (Amiji Decl., Ex. 3 at ¶ 49.)

Next, Dr. Amiji also compared the disclosure of Baker to the composition and formulation of the accused product, NanoBio® Protect, concluding that the embodiment described in paragraph [0232] of Baker [redacted] (*Id*. at ¶ 52.) More specifically, Dr. Amiji has testified that [redacted] (*Id*.) Dr. Amiji further explains that Baker specifically

discloses benzalkonium chloride (BZK) for use in the various nanoemulsions of the invention, in addition to providing additional embodiments incorporating BZK. (*Id*. at ¶ 53 (citing Baker paragraphs [0159] and [0142].) Additionally, Baker describes two other specific oil-in-emulsion embodiments – $W_{80}5EC$ and $W_{20}5EC$ – both of which [redacted] (*Id*. at ¶ 54; citing Baker paragraphs [0137] and [0138].)

Based on his analysis and comparison of the disclosure of the prior art Baker application to the composition of NanoBio® Protect, Dr. Amiji testified "that if NanoBio Protect is determined to satisfy the "HOLD" element (and all elements) of the asserted claims, then the prior art Baker patents necessarily and inherently disclose all elements of the asserted claims as well. In other words, even if the Baker patents do not expressly teach holding the particulate matter in place by adjusting the adhesion and cohesion (or any other elements of the asserted claims), the same formulations and compositions described therein inherently would perform those elements as well." (*Id*. at ¶ 55.)

Notably, Trutek and its infringement expert, Dr. Lemmo, base their infringement theories for NanoBio® Protect with respect to the "HOLD" element of the asserted claims by simply asserting that negatively charged germs "are 'bound' to the nano-droplets" of NanoBio® Protect and therefore, "they are held in

place by the formulation." (Peterson Decl., Ex. 3 at 11; *see also* Ex. 5 at 2 ("The NanoBio Protect product comprises nano-droplets that electrostatically attract and hold 'germs' (i.e., harmful particles).".) Dr. Lemmo provides no further analysis or explanation for how the adhesion and cohesion properties of the formulation of NanoBio® Protect are "adjusted" to provide "adequate impermeability."

"That which infringes, if later, would anticipate, if earlier." *Peters v. Active Mfg., Co*., 129 U.S. 530, 537 (1889); *see also Schering*, 339 F.3d at 1379. Thus, under Trutek's own infringement theories, if the formulation of NanoBio® Protect satisfies element (b) of claims 1 and 2 when applied to the nasal passages, then the same formulation described in the prior art Baker application, which is also intended for use in "nasal and topical forms, including application to the skin or nasal mucosa," necessarily and inherently satisfies that claim element as well. (Amiji Decl, Ex. 1 at ¶¶ 98, 101; Peterson Decl., Ex. 2 at [0013], [0023], [0088], [0189]; Peterson Decl., Ex. 6 at 67.)

Any argument by Trutek that the function of claim element (b) is "newly discovered" by Trutek, or not expressly disclosed in Baker should be disregarded. *See Perricone v Medicis Pharm. Corp*., 432 F.3d 1368, 1377-78 (Fed. Cir. 2005) ("In some cases, the inherent property corresponds to a claimed new benefit or characteristic of an invention otherwise in the prior art. In those cases, the new

realization alone does not render the old invention patentable.") (citing *Atlas Powder Co. v. Ireco Inc*., 190 F.3d 1342, 1347 (Fed. Cir. 1999)).

For all of the foregoing reasons, summary judgment of invalidity based on anticipation by US 2009/0143476 (Baker) is warranted.

V. CONCLUSION

For the reasons stated herein, BlueWillow requests that the Court enter summary judgment in its favor.

Dated: March 28, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on March 28, 2023, I filed the foregoing document and this Certificate of Service with the Court using the ECF system.

/s/ *Nicholas J. Ellis*